

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Pacetti et al.

Group Art Unit: 1762

Serial No.: 10/040,538

Examiner: Erma Cameron

Filed: December 28, 2001

For: A SYSTEM AND METHOD FOR
COATING IMPLANTABLE
DEVICES

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Dear Sir:

On July 3, 2007, Applicants filed an Appeal with the Board of Patent Appeals from the final rejection of Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60 and 71-78. On October 3, 2007, Applicants received an Examiner's Answer including new grounds of rejection for Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78. The following is Applicants' Reply Brief submitted pursuant to 37 C.F.R. §41.41.

STATUS OF CLAIMS

Claims 1-7, 9-26 and 33-78 are pending in the application.

Claims 8 and 27-32 are cancelled.

Claims 7, 12, 14, 37-40, 42, 43, 47 and 61-70 are withdrawn.

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60 and 71-78 are finally rejected.

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78 have been rejected on new grounds in the Examiner's Answer and form the subject of this Reply Brief.

ORIGINAL GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, 48-54, 57-60, 71 and 72 are anticipated by, and therefore unpatentable under 35 U.S.C. § 102(e) over U.S. Pat. No. 6,395,326 to Castro et al. (Castro) (Evidence Appendix A of Appeal Brief).

Whether claims 9, 10, 15, 16, 20, 25, 26, 41, 45, 55, 56 and 73-78 are obvious, and therefore unpatentable under 35 U.S.C. § 103(a) over Castro.

Whether claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78 are obvious, and therefore unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. No. 6,358,556 to Ding et al. (Ding) in view of U.S. Pat. No. 6,407,009 to You et al. (You) (Evidence Appendices B and C of Appeal Brief).

NEW GROUNDS OF REJECTION TO BE REVIEWED IN THIS REPLY BRIEF

Whether claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78 are obvious, and therefore unpatentable under 35 U.S.C. § 103(a) over Ding in view of You.

ARGUMENT

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78 are unobvious, and therefore patentable under 35 U.S.C. § 103(a) over Ding in view of You

The Examiner has rejected claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60 and 71-78 under 35 U.S.C. § 103(a) as obvious over Ding in view of You. The Examiner has modified the rejection of the claims over Ding in view of You from the Final Office Action dated January 5, 2007 which simply maintained the rejection of the claims over Ding in view of You from the previous Office Action dated April 19, 2006. Ding and You were also cited in the Office Actions dated September 30, 2004 and July 5, 2005 for making obvious the present invention.

Applicants' response

I. After relying on Ding to teach an air brush for solvent evaporation in the Office Actions dated September 30, 2004, July 5, 2005, April 19, 2006 and January 5, 2007, the Examiner has now modified the rejection from the Final Office Action dated January 5, 2007 to rely upon room temperature ventilation for solvent evaporation, thereby arguing that exposing a coating to room temperature ventilation for solvent evaporation is the same thing as directing or blowing a gas from a gas dispenser or gas blower onto an implantable medical device, as recited in claims 1, 23, 54 and 73 of the present application. This is clearly not the case.

(1-8) Applicants would like to call attention to the fact that arguments 1-8 as presented in the Appeal Brief, on pages 10-18, are equally applicable and effective in traversing these new grounds of rejection. Arguments 1-8 will not be repeated here but should be considered in addition to the following:

(9) Ventilation, as defined by the Merriam-Webster Dictionary, is “1: the act or process of ventilating; 2 a: circulation of air <a room with good ventilation> b: the circulation and exchange of gases in the lungs or gills that is basic to respiration; 3: a system or means of providing fresh air”.

Ding does indeed disclose a “...coating exposed to room temperature ventilation...” (Col. 3, lines 59-61). However, ventilation, i.e., the circulation of air, is not the same thing as directing or blowing a gas directly onto a stent. Indeed, the term ‘circulation’ denotes the

movement of air in a random manner, not in a directed manner onto an implantable medical device.

(10) With respect to claim 5, the Examiner states that it would have been obvious to one skilled in the art to have selected a specific thermoplastic elastomer, i.e., a species, from the broad class of elastomers, i.e., genus, taught by Ding since a specific member of the broad class would be expected to function in a similar manner. However, “[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.” *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). Rather a case for obviousness must be made upon the facts of the particular case in view of the totality of the circumstance. *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990). The Examiner, however, has put forth no specific reasons why ethylene vinyl alcohol copolymer would have been obvious in view of elastomers taught by Ding. Therefore, the basis for this rejection is without merit.

The Examiner further states that “...it would have been obvious to have substituted one solvent for another with the expectation of equivalent results since the solvent merely evaporates from the coating after application”. This is incorrect. The specific solvent choice is very important since the rate of solvent evaporation can affect the mechanical integrity of a coating as well as the amount of drug that remains in the coating after solvent evaporation. Similarly, the choice of solvent can affect the migration of a drug to the upper layer/surface of the coating. Applicants respectfully submit that the Examiner has again fallen well short of providing a reasonable basis in support of her obviousness position.

(11) With respect to claims 9-10, the Examiner states that while Ding is silent with regard to the distance from the tip of the sprayer to the substrate and the flow rate of coating material, these properties are result-effective variables and “...that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).” In *In re Boesch*, the prior art suggested proportional balancing to achieve desired results in the formation of an alloy. In other words, the claimed parameters in *In re Boesch* were result-effective variables that were recognized by the cited prior art. Ding is distinguishable since Ding does not recognize, in any way, the claimed parameters, i.e., tip distance or flow rate. Ding has absolutely no recognition of the claimed parameters to achieve any kind of results in the solvent removal process.

(12) Furthermore, Applicants submit that You and Ding clearly teach away from each other. It is improper to combine references where the reference teaches away from their combination.” *In re Grasselli*, 713 F.2d. 731, 743, 218 USPQQ 769, 779 (Fed. Cir. 1983).

The Examiner has explicitly stated that the rejection has been modified to rely upon room temperature ventilation as disclosed in Ding. Room temperature ventilation, however, is completely contrary to the teachings of You since You teaches that the temperature inside the deposition chamber is increased by heaters or decreased by coolers (Col. 5, lines 48-51). One reference teaches solvent removal at room temperature while the other reference specifically teaches solvent removal at a temperature other than room temperature. Since You and Ding clearly teach away from each other, in two different instances (*See* argument 8 on page 17 of the Appeal Brief), their combination is improper.

(13) Applicants would also like to address the Examiner’s answers to Applicants’ arguments in the Appeal Brief.

(a) The Examiner indicates on page 15 of the Examiner’s answer that “...both references teach controlling evaporation to achieve even coatings...” Yet on page 10 of the Examiner’s answer, the Examiner states that “Ding et al. lacks a teaching that the temperature of the directed gas is adjusted to control the rate of evaporation”. It is difficult for Applicants to properly respond when the assertions being made by the Examiner are completely contradictory. Applicants concede that the references might be confusing to one skilled in the art, as shown by the Examiner’s statements above, thus one skilled in the art would not have been motivated to look to the combination of Ding and You for guidance in teaching the present invention.

(b) The Examiner has stated on page 16 of the Examiner’s Answer, that the Applicant’s invention is concerned with control of evaporation of solvent to effect a smooth coating, therefore You is reasonably pertinent to the particular problem with which the inventor is involved and it is therefore properly combinable with Ding. Throughout prosecution, the Examiner has been changing what You supposedly concerns (*See* argument 7 on page 15 of the Appeal Brief). In the Office Action dated September 30, 2004, You was concerned with control of evaporation of solvent so as to prevent cracking. In the Office Action dated July 5, 2005, You was concerned with control of evaporation of solvent so as to provide a uniform coating. In the Final Office action dated January 5, 2007, the Examiner yet again changed the U.S.P.T.O.’s position and provided that that motivation is not to correct coating conformity as was previously asserted, but to control the drying aspect of the coating. And now, in the Examiner’s Answer,

the motivation to combine has been changed again, namely to provide a smooth coating. Again, as mentioned in argument 7 on page 15 of the Appeal Brief, the basis for motivation to combine appears to be a moving target changing with each action submitted by the U.S.P.T.O.

(c) The Examiner has stated on page 17 of the Examiner's Answer that Ding and You do not teach away from each other because Ding teaches a coating that covers the entire surface of the stent which is the same thing as the no-gap coating that You wants to achieve. The Examiner has again mis-interpreted the respective teachings of Ding and You. You is not concerned with a coating with no gaps. Rather, You is directed to filling gaps in the substrate. In contrast, Ding does NOT want to fill gaps in the substrate. Therefore, Ding and You are clearly not combinable and actually teach away from each other.

For all of the above reasons, the rejection of claims 1, 23, 54 and 73, and the claims dependent thereon, should be removed.

II. The Examiner appears to have set forth several new grounds of rejection which are not labeled as such in the Examiner's Answer. Applicants, however, would like to address these herein.

(1) The Examiner has stated that Castro "...teaches coating the stents by using a dispenser having a nozzle, which may be an ink-jet head (col. 8, line 59), through which the composition is delivered, which meets the limitation of spraying". This is clearly not the case. An ink-jet head propels precisely measured volumes, i.e., micro-droplets, of a coating composition in a tightly defined stream. In contrast, spraying is used to maximize the effect of a liquid by increasing the total surface area of the liquid for better dispersion over a substrate. These two methods are quite different, and since no where does Castro teach or suggest the "spraying" of a coating composition, this new rejection is without merit.

(2) With respect to claims 3, 33, 44 and 52 which require simultaneous directing of gas and application of the coating composition, the Examiner has stated that since "...Castro et al. teaches that the heating assembly may follow the coating pattern on the prosthesis (col. 11, line 54-col. 12, line 18; col. 18, line 48 – col. 19, line 3)..." this, therefore, meets the limitations of the claims. Applicants are confused by this line of reasoning. Applicants agree that Castro discloses that the heating assembly may follow the coating pattern of the prosthesis. This does not mean, however, that both the gas and coating composition application are necessarily

conducted simultaneously. Simultaneous means that two or more events are occurring at the exact same time. Applicants fail to see how a heating assembly that may follow the coating pattern is equivalent to simultaneous directing of gas and the application of the coating composition.

(3) With respect to claim 33 and the limitation that the blowing of the gas does not affect the direction of the spray onto the device, the Examiner states that "...Castro et al. teaches that the heating nozzle may follow the coating dispenser, thus meeting the limitation that the heating nozzle not interfere with the coating process (col. 11, lines 54-62; col. 18, lines 48 – col. 19, line 3).

First, Castro does not teach that the heating nozzle may follow the "coating dispenser". Rather, Castro teaches that the heating nozzle can follow the "coating pattern" on the prosthesis. One is not the same as the other and the Examiner is incorrect in her reading of Castro.

Second, even if Castro did teach that the heating nozzle followed the coating dispenser, which it does not, this would not mean that the heating nozzle does not affect the direction of the spray onto the device, as required by claim 33. A heating nozzle can follow a coating dispenser and still affect the direction of the spray.

Third, the Examiner has mischaracterized the claimed limitation. Claim 33 recites "...wherein the blowing does not affect the direction of the spray onto the device." The Examiner has read this limitation as "the heating nozzle does not interfere with the coating process". This is a mischaracterization of the claim limitation as the two processes are quite distinct.

Fourth, as stated above, Castro does not teach or suggest spraying and blowing that are conducted simultaneously, as required by claim 33.

For all the above reasons, the rejection of claim 33 should be withdrawn.

(4) With respect to claims 41 and 55, the Examiner states that while Castro is silent with regard to the rotation speed of the stent, the rotation speed is a result-effective variable and "...that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980)." As stated above, in *In re Boesch*, the prior art suggested proportional balancing to achieve desired results in the formation of an alloy. In other words, the claimed parameters in *In re Boesch* were result-effective variables that were recognized by the cited prior art. Castro is

distinguishable since Castro does not recognize, in any way, the claimed parameters, i.e., rotation speed of the stent.

(5) With respect to claims 20, 45, 56, 73, 74 and 78, the Examiner states that "...Castro et al. used the inert gas nitrogen as part of the air that flows from heat source 60 to the stent surface." Castro neither teaches nor suggests the use of nitrogen, or the use of any inert gas. Indeed, the only reference Castro makes to an inert substance is with respect to a biocompatible polymer which is non-toxic and chemically inert. (Col. 12, lines 46-48). The Examiner has failed to point out, again, where nitrogen or an inert gas is taught or suggested by Castro.

(6) With respect to claim 26, the Examiner states that Castro teaches that the coating composition may be heated before being deposited (Col. 3, lines 23-27). Applicants agree that Castro teaches heating the composition. Claim 26, however, teaches a methodology based on a condition, that is, volatility of a solvent, of which Castro fails to teach or suggest.

(7) With respect to claim 75, the Examiner states that the heated gas of Castro would be inclusive of argon. The Examiner, again, provides no reasoning or support for such a conclusion and has simply made a statement without an iota of support or reasoning.

(8) The Examiner has stated, again, that the Declarations of the inventors of the Castro invention, which were submitted on October 13, 2006, are insufficient to overcome the rejections of claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60 and 71-78 because the declarations offer no substantive reasons for their statement that Castro does not teach each of the independent claims. This assertion by the Examiner has been addressed in the Appeal Brief. The Examiner, however, has newly stated that the inventors have not disclosed which aspects of independent claims 1, 23 and 54 are not described by Castro. This is not a requirement for a valid Declaration under 37 C.F.R. 1.132. The inventors have explicitly declared that their own invention, does not teach what is claimed in the independent claims of the present invention. The Declarations are not from just anyone skilled in the art, rather the inventors of the Castro reference itself, thus the Declarations are clearly sufficient to overcome the rejections.

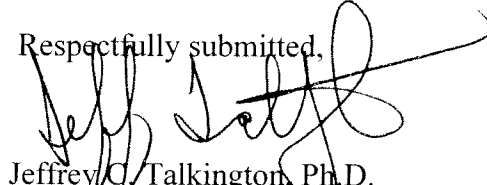
CONCLUSION

The Examiner has failed to set forth a case of *prima facie* obviousness under 35 U.S.C. § 103(a) over Ding in view of You. Furthermore, the new rejections made by the Examiner with respect to Castro have been shown to be without merit. Appellants respectfully request, therefore, that the Board allow the application to proceed to issue.

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Respectfully submitted,



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